Rules Writing Workshop Optometry Oral Medication September 8, 2003

A rules development workshop was called to order at 6:00 p.m., Monday, September 8, 2003, by R. Richard Ryan, O.D. The purpose of the workshop was to facilitate development of Board of Optometry rules to implement Chapter 142, Laws of 2003. Chapter 142 authorizes qualified optometrists to prescribe drugs administered orally and to administer epinephrine by injection. The meeting was held at the Department of Health, 20435 72nd Avenue South, Suite 200, Kent, Washington 98032.

ATTENDEES: R. Richard Ryan, O.D., Chair, Board of Optometry

Thomas Riley, O.D., Board of Optometry Jeffrey Sutro, O.D., Board of Optometry

Robert W. Nash, M.D., Washington Academy of Eye Physicians &

Surgeons (WAEPS)

Aaron Weingest, M.D., WAEPS David Epley, M.D., WAEPS

Susie Tracy, Lobbyist, Representing WAEPS Tim Layton, Lobbyist, Representing WAEPS

Lori Youngman, O.D., Optometric Physicians of Washington (OPW)

Mike McCowan, O.D., OPW David Savage, O.D., OPW

Earl Tower, Lobbyist, Representing OPW

Judy Haenke, Program Manager, Department of Health

Melissa Quirke, Administrative Assistant, Department of Health

Richard Ryan, O.D. introduced Optometry Board members Thomas Riley, O.D., and Jeffrey Sutro, O.D. who joined him in facilitating the meeting. Dr. Ryan explained that the purpose of the meeting was to allow an opportunity for interested persons to comment and provide recommendations on rules related to required training to prescribe oral medication and to administer epinephrine by injection, and on a proposed drug formulary.

Draft documents for the purposes of discussion included:

- June 25, 2003, Working Draft for Medications for Use by Optometrists in Washington State (Drug Formulary)
- June 25, 2003, PUCO/SCCO Advanced Ocular Therapeutics Course 28 hours including an Emergencies & Injection Workshop 4 Hours Total

Dr. Ryan asked for comments and recommendations from those in attendance.

Following is a summary of comments and recommendations made by those who attended the meeting. The summary does not necessarily represent the order in which the comments and recommendations were made.

- Robert Nash, M.D., President of Washington Academy of Eye Physician and Surgeons (WAEPS) spoke in favor of lists of drugs where indicated rather than broad categories. Indications for a list vs. a category would be those drugs which have a higher known risk of side effects, toxicity, and/or adverse reactions. Antibiotics would be an appropriate category (with an exception for the more dangerous members such as vancomicin) whereas antifungals, due to toxicity issues, would be more appropriately listed individually.
- Categories vs lists was discussed further. Comments included:
 - o There are some drugs in some categories that do not have an ocular application.
 - Other states have extensive lists of drugs within each category which has made it difficult for practitioners to prescribe and to bill for services.
 - The outcome of this rules process is to develop rules that are good for the people of the state of Washington.
 - Categories of drugs would be less burdensome and would not require rules hearings or other processes to add a drug to a list.
- Jeffrey Sutro, O.D., discussed a process for review of newly approved drugs which would include consultation with the Board of Pharmacy, input from stakeholders, final approval of the Board of Optometry and formal hearing for adoption.
- David Epley, M.D. expressed concern that pediatric care and care of other restricted patient categories be sufficiently addressed in the rules, in the guidelines and in the required course curriculum.
- Adding a medication to the approved formulary was discussed at length.
 Comments included:
 - A clear process for adding a medication or medication category is needed.
 - o It may be possible to add an agent within a class without a formal rules hearing, but a hearing would be required to add a class of drugs to the formulary.
 - The initial rules could be developed with a clause to allow for quarterly meetings with affected stakeholders to discuss newly approved drugs.
 - For categories, approved drugs within the category that are approved for ocular use should be considered approved without formal hearing.
 - Orugs being considered for approval by the FDA are known in advance of the final approval. The rules hearing process could be initiated when the drug being considered for approval reaches Pre Market Approval (PMA) status.

Thomas Riley, O.D. led a line by line review of the current proposed draft formulary. The proposed formulary follows with comments inserted and highlighted.

WAC () Drug formulary for the prescription, dispensing or administration of oral medications includes:

- 1. Antibiotic agents including but not limited to: Penicillins, Cephalosporins, Quinolones, Tetracyclines, Macrolides, Lincosamides, and Sulfonamides.
 - Should be a category, excluding vancomicin
- 2. Antiviral agents
 - This is an area where there may be new drugs.
 - Antivirals should be a category, with exclusions.
 - Need to be aware that there are some things that should be coordinated with the primary care provider.
 - Guidelines should include caution against misuse of antivirals.
- 3. Antifungal Agents
 - Antifungals are not used often a list with guidelines is preferred
- 4. Antihistamines including but not limited to: Non-selective Alkylamines, Ethanolamines, Phenothiazines, Piperazines, and Piperidines. Also includes Peripherally-selective Piperazine and piperidines
 - Categories are preferred
- 5. Decongestant agents including but not limited to: all Arylalkylamines.
 - Categories are preferred
- 6. Dry eye agents
 - A list which includes saligen is preferred
- 7. Gastrointestinal Agents
 - Intended use is for GI distress caused from a reaction to medication to treat angle closure
 - Change to anti-emetics for distress from medications used for angle closure
 - Listing is preferred.
 - Guidelines should have information about coordination with the PCP.

- 8. Diagnostic Agents such as oral Fluorescein Sodium and all dyes necessary in ordering appropriate radiology studies.
 - Not clear which medications would be included in this category.
 - Fluorescein Sodium is an injectable rather than an oral drug.
- 9. Diuretics for use in Anti-Glaucoma Conditions
 - Clarify use in guidelines
- 10. Non-Steroidal Anti-inflammatory agents
 - Categories are preferred.
 - Potential problems are possible with all drugs in this group
 - Some restrictions may be needed in light of abuse potential (Ultram) and nephritic toxicity. These will be discussed further with the Board of Pharmacy.

11. Antianxiety agents

- Should be used exclusively in pre-op situation
- Used for procedures such as punctual plugs
- Limit to a few common drugs for in-office use
- Concern has been expressed by liaisons representing the Board of Pharmacy for abuse potential and that certain agents in this category may not be appropriate for the intended usage (primary in-office procedure anxiety reduction) due to their time of onset and duration of action.
- Need informed consent prior to procedure
- 12. Antiplatelet agents for emergent amaurosis fugax or retinal vascular disease.
 - You may be sued for malpractice for anything but aspirin
 - It is unclear and not yet demonstrated whether aspirin is indicated for a stroke
 - Consultation with the PCP is necessary
- 13. Any FDA approved agents with ocular applications

WAC () Drug Formulary for Controlled Substances limited to Schedule III, IV, and V includes:

Schedule III Narcotics: Such as Acetaminophen with Codeine, Aspirin with Codeine, Fiorinal with Codeine, and Acetaminophen with Hydrocodone. Hydrocodone can only be dispensed with concentration maximum of 5 mg per dose.

- It has been suggested that hydrocodone be dispensed with a maximum concentration of 5 mg per dose in response to concern of drug seekers.
- The authorizing statute already limits the administration of hydrocodone to seven days per occurrence. No further limitation is needed.
- 2. Schedule IV Nacotics includes: Acetaminophen with Propoxphene Napsylate, Aspirin with Pentazocine, Acetaminophen with Pentazocine, and Naloxone with Pentazocine
- 3. Schedule IV Antianxiety/Sedative include: Benzodiazepine Derivatives including Alprazolam, Clorazepate, Chlordiazepoxide, Diazepam, Lorazepam, and Oxazepam.
- 4. Schedule V Narcotics include: Acetaminophen with Codeine limited to 120mg of Acetaminophen and 12 mg of Codeine
- WAC () Drug formulary for injectable substances includes: 1. Administration of epinephrine by injection for the treatment of anaphylacty without consulting the patient's surgeon.
- 2. May not prescribe, dispense, or administer a controlled substance schedule I or II
- 3. May not prescribe, dispense, or administer a controlled substance, schedule III to IV for more than seven days for any patient for a single condition or associated pain. If additional treatment is needed, the patient must be referred to a physician.
- 4. May not perform injections or infusions excluding administration of epinephrine by injection for the treatment of anaphylactic shock.

Thomas Riley, O.D. led a line by line review of the current proposed draft educational course which follows with comments inserted.

Working DRAFT June 25, 2003

PUCO/SCCO ADVANCED OCULAR THERAPEUTICS - 28 HOURS

PART A - DIDACTIC INSTRUCTION - 16 HOURS TOTAL

Basic Principles of Systemic Drug Therapy - 2 hrs

• Change this portion of the course to one hour.

Side-Effects, Adverse Reactions and Drug Interactions in Systemic Therapy - 1 hr

Review of oral pharmaceuticals – 4 hrs

- Change to 5 hours and Basic Principles to one hour
- Prescription writing
- Legal regulations in oral prescription writing
- Systemic Anti-bacterial in Primary Eye Care
- Systemic Anti-viral in Eye Care
- Systemic Anti-fungal in Eye Care
- Systemic Antihistamines and Decongestants and their uses in Eye Care
- Gastrointestinal agents and their use in eye care
- Management of post herpetic neuralgia
- Systemic Diuretics and their management of Elevated IOP
- Inert diagnostic dyes (sodium fluorescein (oral form only)
- The management of emergent amaurosis fugax or retinal vascular disease.
 - Rather than using the term "amaurosis fugax, use "optic nerve injuries or conditions", or other similar language
- Systemic Epinephrine

Review of systemic medications in Ocular Pain Management- 2 hr

- Prescription writing
- Legal regulations with scheduled medications
- Systemic non-steroidal anti-inflammatory drugs (NSAIDS)
 - Move to Review of oral pharmaceuticals
- Systemic non-scheduled analgesics
 - Move to Review of oral pharmaceuticals.
- Systemic scheduled analgesics

Review of oral medications used for sedation and anti-anxiety properties in eye care-1hr

Anti-anxiety agents

Scheduled anti-anxiety and sedative medications and their role in eye care

Washington state formulary for oral medications in primary eye care - 1 hr

- Delete the list of drugs use Washington State Formulary for Oral Medication)
- Antibiotic agents
- Antiviral agents
- Antifungal agents
- Antihistamines
- Decongestants
- Dry eye agents
- Gastrointestinal agents
- Diagnostic agents
- Diurnal agents
- Non-steroidal anti-inflammatory drugs (NSAIDS)
- Anti-anxiety agents
- Antiplatelet agents
- Scheduled III-V Narcotic agents
- Scheduled III-V Anti-anxiety/Sedative agents

Applied Systemic Pharmacology: Grand Rounds in Ocular Disease Mgmt. - 4 hr.

- Eye lid & Adnexal tissue
- Lacrimal System & Peri-orbital sinuses
- Conjunctival & Corneal disorders
- Iris and Anterior Chamber Disorders
- Posterior Segment Disorders
- Optic Nerve Disease
- Peripheral Vascular disease and its relationship with ocular disease
- Atherosclerotic disease
- Other/course review

WRITTEN EXAM – 1 hr. We are not considering this 1-hour test part of the education

PUCO/SCCO ADVANCED OCULAR THERAPEUTICS PART B - SUPERVISED CLINICAL INSTRUCTION - 8 HOURS TOTAL PHYSICAL ASSESSMENT WORKSHOP

- Vital Signs 1.5 hr.
- Auscultation 2.5 hr.
- Ear, Nose & Throat 2 hr.
- <u>Screening Neurological Exam</u> 2 hrs

PART C - EMERGENCIES & INJECTION WORKSHOP - 4 HOURS TOTAL

<u>Review of Urgencies, Emergencies, & Emergency-use Agents</u> – 2 hrs Review Pharmacology of epinephrine

Ocular urgencies

- Thermal burns Direct and photosensitivity-based ultraviolet burn
 - Electrical injury
 - Cryo-injury and frostbite
 - Stings and bites
 - Punctures, perforations, and lacerations

General urgencies & emergencies

- Anaphylaxis
- Hypoglycemic crisis
- Narcotic overdose

<u>Injections workshop</u> 2 hours <u>Instrumentation</u>

- Informed consent
- Preparation (patient and equipment)
- Epi-pen injections
- <u>Intramuscular injections</u> (must demonstrate proficiency)
- <u>Starting an IV</u> (must demonstrate proficiency)
- Sub-cutaneous injections
 - Consider adding a requirement for CPR for endorsement to administer epinephrine.

FUTURE RULE WRITING WORK SHOPS

Board of Optometry Meeting: September 26, 2003

If you can not attend the meeting, you may send comments to:

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